PCT/CH 2004/000466

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Confirmation

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PCT REQUEST

278-1.B.WO-P

Original (for SUBMISSION) - printed on 22.07.2003 04:29:28 PM

0	**For receiving Office use only**	
0-1	International Application No.	PCT/CH 03 / 00502
0-2	International Filing Date	24. Juli 2003 (24.07.03)
0-3	Name of receiving Office and "PCT International Application"	RO / CH - Demanda international PCT
0-4	**Form - PCT/RO/101 PCT Request**	
0-4-1	Prepared using	PCT-EASY Version 2.92 (updated 01.04.2003)
0-5	**Petition** The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty	
0-6	**Receiving Office (specified by the applicant)**	Swiss Federal Intellectual Property Institute (RO/CH)
0-7	**Applicant's or agent's file reference**	278-1.B.WO-P
I	**Title of invention**	METHOD AND APPARATUS FOR TOTAL HIP ARTHROPLASTY
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V	Designation of States	
V-1	Regional Patent (other kinds of protection or treatment, if any, are specified between parentheses after the designation(s) concerned)	AP: GH GM KE LS MW MZ SD SL SZ TZ UG ZM ZW and any other State which is a Contracting State of the Harare Protocol and of the PCT EA: AM AZ BY KG KZ MD RU TJ TM and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT EP: AT BE BG CH&LI CY CZ DE DK EE ES FI FR GB GR HU IE IT LU MC NL PT RO SE SI SK TR and any other State which is a Contracting State of the European Patent Convention and of the PCT OA: BF BJ CF CG CI CM GA GN GQ GW ML MR NE SN TD TG and any other State which is a member State of OAPI and a Contracting State of the PCT
V-2	National Patent (other kinds of protection or treatment, if any, are specified between parentheses after the designation(s) concerned)	AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH&LI CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NI NO NZ OM PG PH PL PT RO RU SC SD SE SG SK SL SY TJ TM TN TR TT TZ UA UG US UZ VC VN YU ZA ZM ZW
V-5	Precautionary Designation Statement In addition to the designations made under items V-1, V-2 and V-3, the applicant also makes under Rule 4.9(b) all designations which would be permitted under the PCT except any designation(s) of the State(s) indicated under item V-6 below. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit.	
V-6	Exclusion(s) from precautionary designations	NONE
VI	Priority claim	NONE
VII-1	International Searching Authority Chosen	European Patent Office (EPO) (ISA/EP)

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VIII	**Declarations**	Number of declarations	
VIII-1	Declaration as to the identity of the inventor	-	
VIII-2	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent	-	
VIII-3	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application	-	
VIII-4	Declaration of inventorship (only for the purposes of the designation of the United States of America)	-	
VIII-5	Declaration as to non-prejudicial disclosures or exceptions to lack of novelty	-	
IX	**Check list**	number of sheets	electronic file(s) attached
IX-1	Request (including declaration sheets)	4	-
IX-2	Description	8	-
IX-3	Claims	2	-
IX-4	Abstract	1	EZABST00.TXT
IX-5	Drawings	12	-
IX-7	TOTAL	27	
	Accompanying items	paper document(s) attached	electronic file(s) attached
IX-8	Fee calculation sheet	✓	-
IX-17	PCT-EASY diskette	-	Diskette
IX-19	Figure of the drawings which should accompany the abstract	6c	
IX-20	Language of filing of the international application	English	
X-1	Signature of applicant, agent or common representative		
X-1-1	Name (LAST, First)	ROLAND, André	

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10-3	Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application	
10-4	Date of timely receipt of the required corrections under PCT Article 11(2)	
10-5	International Searching Authority	ISA/EP
10-6	Transmittal of search copy delayed until search fee is paid	

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11-1	Date of receipt of the record copy by the International Bureau	

METHOD AND APPARATUS FOR TOTAL HIP ARTHROPLASTY

Field of the invention

This invention relates generally to the field of prosthetics and in particular to methods and apparatus for positioning an implant relative to a bone so as to achieve a desired orientation. More specifically, the invention is directed towards instrumentation and surgical techniques which ensure an accurately aligned acetabular prosthetic element. But it may be used for the orientation of components elsewhere. The method takes into consideration the adequate orientation of the pelvis to assure the desired position of the acetabular cup with respect to the direction of the force of gravity as determined by a bulls eye level or an electronic device that identifies the latter, it also allows to measure the orientation of a cup that is already in place.

The instrument may be calibrated to assure a desired orientation depending on the design of the cup and the anteversion of the femoral stem. All this in order to obtain maximum impingement free range of motion. This improves with simple means the accuracy and precision particularly of the acetabular cup that is lacking with present methods. A well known fact in clinical epidemiology states that any effort to improve precision improves accuracy.

Background of the invention

Improved orthopaedic procedures have made joint replacement commonplace. In total hip arthroplasty, both the femoral or ball aspect of the joint as well as the acetabular or socket portion are replaced with prosthetic implants. A wealth of references exist in this field, and many patents have been issued with respect to the implants themselves, as well as the tools used in such procedures and various methods.
Orientation of the femoral stem is universally considered as less complex. Orientation of the acetabular component is far more complicated, and techniques designed to improve it are far less developed. Some of the existent techniques are inadequate due to the complexity. The literature has shown the lack of concordance even among experienced surgeons when estimating intraoperative orientation of the acetabular cup with standard techniques.

Some techniques developed for computer assisted surgery are promising but present limitations of their own and it may some time before patients can benefit. Its world wide availability will be limited due to high costs and special training required. There are several reasons for the lack of progress in this area. The orientation of the acetabular cup requires an adequate orientation of the pelvis in three planes. Its anatomy may be altered by disease, even severely altered in cases of revision arthroplasty. Present mechanical techniques use the floor level and the longitudinal axis of the operating table as a reference. The initial position of the pelvis in three planes (Yaw, Roll and Pitch) is ignored and therefore can lead to errors. The initial position is also known to change significantly during the intervention. The second problem with standard guides is the assumption that the orientation of the pelvis in terms of flexion/extension is always the same with respect to the axis of the table. Additionally, standard mechanical guides rely on visual references and therefore lack precision.

Many surgeons orient the acetabular component through "feeling", a technique that has also been shown in the literature to be highly inaccurate and imprecise even in the most experienced hands.
Lack of optimal orientation of both components acetabular cup and shaft as a couple, has been shown to result in limited range of motion due to impingement which leads to dislocation, early wear and loosening of the components.

The situation has lead to the use of imperfect techniques associated with prosthetic acetabular implantation, often involving the use of manually operated instrumentation which rely only on the surgeons hand and eye coordination to install the implant and occasionally relying on visual markers. Existing tools in this area are described in U.S Pat. Numbers xxxxxxxxxxxx

Studies have confirmed the importance of precise and matching positioning of both the acetabular and the femoral component. There is increasing awareness that improved reproducibility in component orientation fosters improved range of motion before impingement, implant longevity, reduced wear of the acetabular component and lower rates of dislocation.

The need remains for simple to use and inexpensive instrumentation and techniques that can be applied to any type of hip prosthesis in either lateral or dorsal decubitus. The technique and instruments described improve the orientation of components even in the hands of less experienced surgeons.

Clinical epidemiology studies have extensively studied the sources of random errors (Lack of precision) and systematic errors (Lack of accuracy) for diagnostic or measuring tools in clinical practice. They have been divided into three aspects:
-Observer variability
-Subject variability (Differences among patients)
-Instrument variability

The invention focuses on studying sources of error of acetabular orientation from a Clinical Epidemiology point of view in order to provide improved precision and accuracy by reducing instrument variability. Designing Clinical Research, An Epidemiologic Approach, Hulley. Williams and Wilkins 1988.)

Sources of Systematic Errors (Adapted to standard mechanical guides for cup orientation)

- Instrument Variability (guide used)
  - Differences resulting from the instrument used.
    - Eye coordination in two different planes
    - Does not take into account pitch angle for axis of anteversion (but orientation of the table)
    - Use of a mechanical guide that can not be calibrated with a gold standard.

Having identified the problem, the guide was created as a solution that complies with the standard strategies of clinical epidemiology for improving reliability of measuring instruments.

Strategies to increase precision (avoid random error)
(Designing Clinical Research, An Epidemiologic Approach, Hulley. Williams and Wilkins 1988.)

- Standardising the methods for placement of the femoral and acetabular components.
- **Training the surgeons in the standard techniques: Guide with Gravity Assisted Navigation System facilitates and improves training of surgeons.**
- **Improve patient positioning: Guide with Gravity Assisted Navigation System facilitates and improves patient positioning.**
- **Refining the instruments used for orientation of the components: making it easier to use allowing use by looking at it from different angles.**
- **Automating the instrument (avoid human error)**
- Repeating the measurement

Strategies to increase Accuracy (avoid bias)
(Designing Clinical Research, An Epidemiologic Approach, Hulley. Williams and Wilkins 1988.)

- Standardising the methods in an operations manual.
- **Training the surgeons in the standard (i.e reproducible) techniques.**
- **Improve patient positioning**
- **Refining the instruments used for orientation of the components.**
- **Automating the instruments**
- **Calibration of the instruments and the "position of the patient" (WITH A GOLD STANDARD)**

Brief description of the drawings.

Fig 1a, 1b, 1c,
Level for positioning of pelvis in strict lateral decubitus using as a reference the Antero superior iliac spines ASIS and the direction of the force of gravity.
1-External solid support made of strong material.
2-Sliding arm along the support 1 to adapt apparatus to different distances between antero superior iliac spines ASIS.
3-Fixed bar of the same length as 2
4-Pelvis
5- Supports for stability of bars 2 and 3.
6- Spirit level for controlling « ROLL »
7-Bars that must come into contact with ASIS through palpation with middle and annular fingers allowing to identify the pelvic position through direct palpation of these anatomic repairs.
8-Handles for the thumbs allowing palpation at the same time with middle and annular fingers.

Fig 3a, 3b.
Plastic Bulls'eye level
1-Air bubble.
2-Centre of the level.

3-Fluid filled transparent level.
4-Support of the level. Made of plastic sterilized with Gamma Rays.

Fig 4a, 4b.
Another set of drawings showing the guide shown on Fig 6.
1-Support allowing connection to either reamer or cup positionner.
2-Optional screw for fixation of 1.
3-Pointer for Antero Superior Iliac Spine ASIS
4-Bulls' eye level holder that allows bending for either calibration of the apparatus or measuring the orientation of a cup in a patient during surgery.
5-Pins for holding the Bulls' eye level.

Fig 5a, 5b.
Apparatus for calibrating desired orientation or for measuring a given orientation with instrument described in Fig 4. (ORTHOFRIEND)

1-Bulls'eye level to assure adequate orientation of the instrument with respect to the direction of the force of gravity.
2-Level adjustment for the instrument.
3- Calibration arm for right hip.
4-Axis of rotation for anteversion.
5-Scale for measuring anteversion.
6-Axis of rotation for abduction.
7-Scale for abduction.
8-Abduction and anteversion will be read off the edges of this disk.
9-Threaded hole for fixing cup positioner with guide for gravity assisted orientation of the cup for calibration.

Fig 6a
Guide for Gravity Assisted Orientation of the cup.
1-Support to be hand held with the reamer tool or cup positionner.
2-Pointers to be aligned with fingers to the subcutaneous ASIS.
3-Bulls'eye levels to precisely determine the direction of the force of gravity for orientation of the cup in the right or left hip.
4-Supports can be bent to calibrate the guide to a desired orientation using instrument described in Fig. 5a, 5b or to record the orientation of a cup in a given patient and then measure it with the same instrument 5a, 5b.

Fig 6b,
Orientation of the pelvis in lateral decubitus. Axial view showing anteversion of the cup. Guide for Gravity Assisted control of pelvic position and cup orientation.

1,2,3-Support for sterile bulls' eye level. (or electronic vs electromagnetic device indicating direction of the force of gravity or floor level)
4-Right ASIS Antero Superior Iliac Spine.
5-Left ASIS Antero Suprior Iliac Spine.
6-Force of Gravity
7-Handle of Standard Cup Positionner.
8-Guide for Gravity Assisted Navigation System with support for Bulls'eye levels,

9-Bulls'eye level for right hip. When centered, desired orientation has been obtained.
10-Pointer that must be aligned to the ASIS which is easily palpated percutaneously.
Fig 6c
Positioning of patient in strict lateral decubitus.

1-Patient in strict lateral decubitus.
2-Bulls'eye level at "zero" after patient installation controlling "roll"and "yaw" of the pelvis.
3-Shanz pin and clamp of a Hoffman II hand external fixator, allowing fixation to the iliac crest through Shanz Pin (commercially available)
4-Gravity Assisted Navigation Guide is held against the shaft of the cup impactor. It can also be used with the reamers so that the acetabular cavity is prepared with the desired orientation.
5-ASIS Antero Superior Iliac Spine
6-Acetabulum
7-Bulls'eye level for Left Hip
8- Bulls'eye level for Right Hip
7 and 8 Identify precisely the direction of the force of gravity giving the adequate orientation in abduction and anteversion previously calibrated at manufacture or by the surgeon taking into account two points reference. Thanks to these two points (5,6) the flexion/extension of the pelvis the "Pitch" is taken into account.
9- Force of Gravity.

Fig 7
Antero posterior View of the pelvis showing cup abduction.

1- "Real Time" control of pelvic orientation with the bulls eye level fixed to the pelvis as shown on Fig 6b.
2- Pointer of the guide aligned to the ASIS Antero Superior Iliac Spine.
3- Ideal Orientation is easily visualized fronm a single perspective.
4- Hammering once desired orientation has been obtained.

Fig 7a
-ORTHOFRIEND- calibration instrument for the guide for Gravity assisted orientation of the cup and Measuring instrument for measuring the orientation of a cup.

1-Bulls' eye level to assure adequate placement of instrument
2-level adjustements for the instrument.
3-calibration arm for right hip.
4-axis of rotation for the anteversion.
5-Scale for measuring anteversion.
6-Axis of rotation for abduction.
7-Scale for abduction
8-Abduction and anteversion to be read off the edges of the disk.
9-Threaded hole for fixing cup positioner for "Gravity assisted Calibration of the Guide".

Fig 7b
Use of the Calibrating instrument "(ORTHOFRIEND tm)"
1-Bulls'eye level for Left hip
2-Bulls'eye level for Right hip
3-Bulls' eye level can be bent (made of bendable material) centering the bubble and thus recording the desired orientation.

4-Desired anteversion or "recorded" anteversion is read off these edges.
5-Desired abduction or recorded abduction is read off these edges.

INSTRUCTIONS OF USE

1- Install the patient in strict lateral decubitus and fix the pelvis in the usual fashion with the pubic and sacral supports.

2- Control that the ASIS are parallel to the direction of the force of gravity with instrument in figure 1a,1b,1c. This controls the initial position of the pelvis in "Roll" and "Yaw"

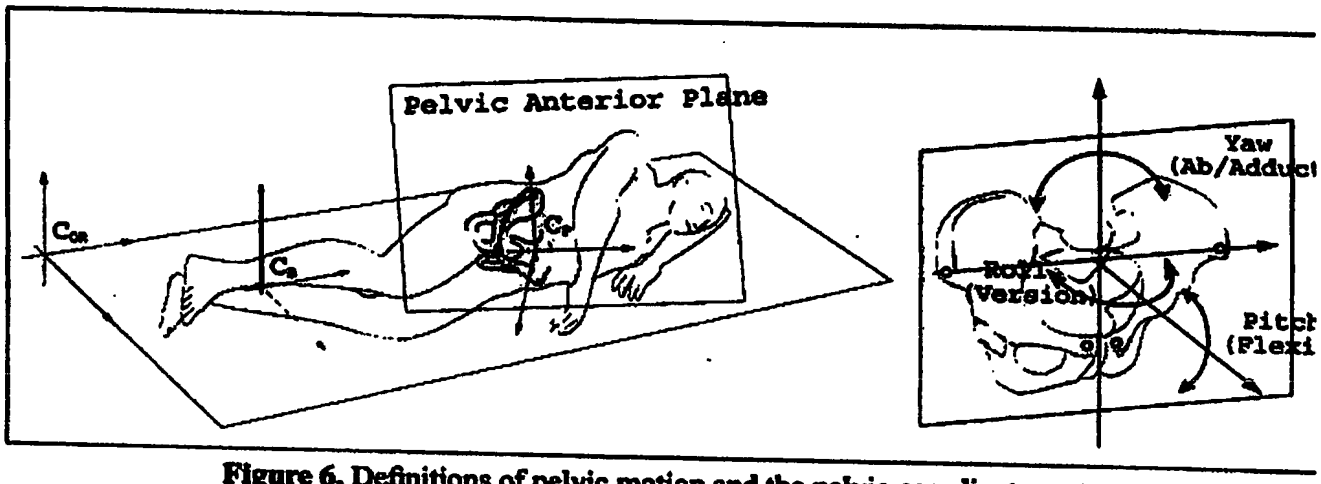
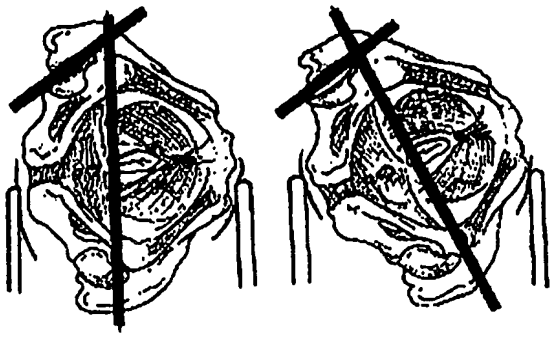


Figure 6. Definitions of pelvic motion and the pelvic coordinate system using an anterior pelvic plane defined by the anterior superior iliac spines and symphysis pubis.

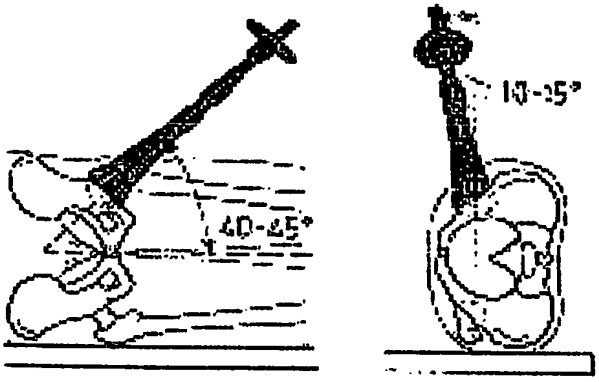
3-Proceed to disinfection and draping of the extremity. Through a two centimetre skin incision over the iliac crest implant a Shanz pin.
4- Using a clamp from a Hoffman II external hand fixator, set to zero the Guide for Gravity Assisted control of pelvic position. Fig 6b,6c. These will allow resetting of the pelvis to the initial desired position with respect to the direction of the force of gravity at key points during surgery, acetabular reaming and cup impaction. This avoids correct positioning with respect to direction of the force of gravity but erroneous with respect to the pelvis.



5- Continue with your usual surgical technique until you get to the last reamer. Control that the pelvis is in the initial desired position by looking at the Guide for Gravity Assisted control of pelvic position and correct if necessary by moving the pelvis until the bubble is set to zero. (Fig 6b item 3)

6-If you desire the factory pre calibrated guide, place the last reamer inside the acetabulum, place the pointer of the pointer Guide for gravity assisted orientation of the cup. Fig 6a,6b. over the easily palpable Antero Superior Iliac Spine (ASIS), (fig 6b item 4) move the instrument until the bubble is centered identifying with precision the direction of the force of gravity. (Fig 7 Item3)

7-Run the reamer in that position to obtain a cavity in the precalibrated orientation (Abduction and Anteversion).



8-To place the final cup, adapt the Guide for gravity assisted orientation of the cup to the cup positioner, repeat step 5 and then 6.

9-To measure the cup orientation in a patient, adapt the cup positioner to the cup, control that the pelvis is adequately oriented with the Guide for Gravity Assisted control of pelvic position. (Fig 7 item1) and correct if necessary. Align the pointer with the ASIS and bend the support of the Bulls eye level in the Guide for gravity assisted orientation of the cup until the bubble is centered identifying with precision the direction of the force of gravity. (Fig 7 item3)

10-Screw the cup positionner on to the Calibrating instrument for the Guide for Gravity Assisted control of pelvic position as shown on the Fig 7b.

11- Move the instrument until the bubble is centered identifying the direction of the force of gravity while placing the pointer over one of the arms that simulate the ASIS location and read from the disc the corresponding abduction and anteversion. Fig 7a,7b.

ADVANTAGES

-Enhanced Accuracy and Precision of acetabular cup orientation, both abduction and anteversion of the cup by providing real time pelvic and acetabular cup orientation.
-Allows precise reaming of the cavity in the desired orientation.
-Control of the desired orientation of the pelvis in strict lateral decubitus or strict dorsal decubitus hence controlling the pelvic position in the three planes at the time of cup insertion.
-Ease of use without requiring the surgeon to look at the guide from a specific point of view. Seeing the bubble or bulls' eye level is enough to determine the orientation.
-Its low cost and no training needed making it available to surgeons even in developing countries.
-No more time required than with existing techniques.
-Allows the surgeon to calibrate his instrument to the desired orientation (abduction and anteversion)
-Orientation of acetabular cups already in situ can be reliably measured with the guide.
-The adaptability to existing ancillary and current surgical techniques in dorsal decubitus, lateral decubitus, cemented, uncemented, anterolateral or posterolateral approaches.

Instead of using bulls' eyes or spirit levels, electronic devices identifying the direction of the force of gravity may be adapted to all the instruments mentioned.

CLAIMS

1- An apparatus for improving the orientation of the pelvis in strict lateral decubitus with respect to the direction of the force of gravity in two planes, (Fig 1a,1b,1c) therefore controlling the roll and yaw positions of the pelvis reducing the probability of errors during pelvic positioning. It consists of a hand held device provided with a fluid level or a bulls eye level(or an electronic device for identifying the direction of the force of gravity) that when applied to the anterosuperior iliac spines in lateral decubitus allows positioning in strict lateral decubitus. The apparatus is non sterile, reusable and assures high precision and accuracy.Through intraoperative augmented reality the constant direction of the force of gravity and the design described makes it a Gravity Assisted Navigation System. It could also be manufactured as a reusable instrument.

2- An apparatus consisting of a bulls' eye sterile level fixed to a universal joint that is fixed to a standard Shanz pin fixed percutaneously to the iliac crest. Figs 2a, 2b, 3a, 3b As shown in use in Fig 6b This way the ideal initial position (strict lateral or dorsal decubitus) identified with apparatus in Fig 1a, 1b,1c. is monitored throughout the intervention with respect to the direction of the force of gravity as described here below.

3- The universal joint allows the level to be set to zero identifying the position of the pelvis at the start of the operation controlling the roll and yaw.(The position identified in step 1) The apparatus is in part sterile disposable and the rest to be re-sterilized with the instruments or single use. It allows precise reproduction of the orientation of the pelvis with respect to the direction of the force of gravity. Fig 6b,6c

4- A sterile bulls eye level fixed to an ancillary that by taking two points of reference, the centre of the acetabulum and any other, preferably the antero-superior iliac spine percutaneously, reproduces precisely and accurately the desired orientation of the cup in terms of abduction and anteversion with respect to the anatomic plane of the pelvis. Fig 4a,4b,6a as it is shown in use in fig 6b. The precise orientation of the pelvis must also be assured so that orientation of the cup with respect to the pelvis is the desired one. The apparatus could be completely re-sterilized with a main frame made of metal or in part sterile disposable and the rest to be re-sterilized with the instruments.

5- A simple aid adapted to standard rasps and impactors for the femoral stem improving the precision of the visual estimation of the femoral anteversion with respect to the axis of the leg in flexion. This apparatus to be re-sterilized with the instruments, could also be made for single use. Precision in the orientation of the stem is generally considered in the literature as less problematic. Fig 4c. (Just for information it is not the main aspect) Can be included as a secondary improvement)

6- An apparatus to be re-sterilized or for single use. Fig 5a,5b, 7a,7b It consists of a base placed on the table with the rest of instruments. Horizontal orientation is assured by a bulls eye level . A cup with a thread in its apex like standard metal backs allowing for standard cup driving shafts to fit in. This cup is fixed to two rotating concentric rings that allow rotation of a semi sphere in the axis of anteversion and abduction. Apparatus 4 is fixed to the driving shaft, the pointer for the ASIS is hooked to one of the 2 markers provided for Right or Left. Desired orientation is read off the surface of

the semi sphere. The fixing device of the bulls eye level attached to the apparatus 3 is bent to obtain the bubble at the centre. It can then be used to reproduce this orientation in a pelvis or vice-versa, to measure the orientation of a cup in a pelvis.

ABSTRACT

Method and kit of apparatus to facilitate the positionning of prosthetic elements in total hip arthroplasty, femoral and acetabular component so as to obtain the desired orientation. it can also be used to measure precisely the acetabular orientation obtained.

The kit is composed of a number of items to assure:

1-adequate placement of the pelvis in lateral decubitus for the surgical intervention. fig 1a, 1b, 1c.

2-control of the desired position of the pelvis in either strict lateral decubitus or dorsal decubitus throughout the intervention with respect to the direction of the force of gravity in two planes by using a bulls' eye level or an electronic device that identifies the direction of the force of gravity.

3-precise anteversion and abduction of the acetabular cup with respect to the chosen position of the pelvis in lateral or dorsal decubitus, taking into consideration the pelvic flexion/extension. the apparatus allows calibration to reproduce the orientation with respect to the direction of the force of gravity and an axis within the pelvis obtained by taking two anatomic points within it, the centre of rotation of the hip and any second anatomic reference within the pelvis e.g. the anterosuperior iliac spine (asis).

4-precise identification of the anteversion of the femoral stem. fig 4c

5-measuring of the final orientation of an acetabular cup with instrument shown in figs 6a, using a calibrated additional instrument. fig 7a, 7b

Fig 1a

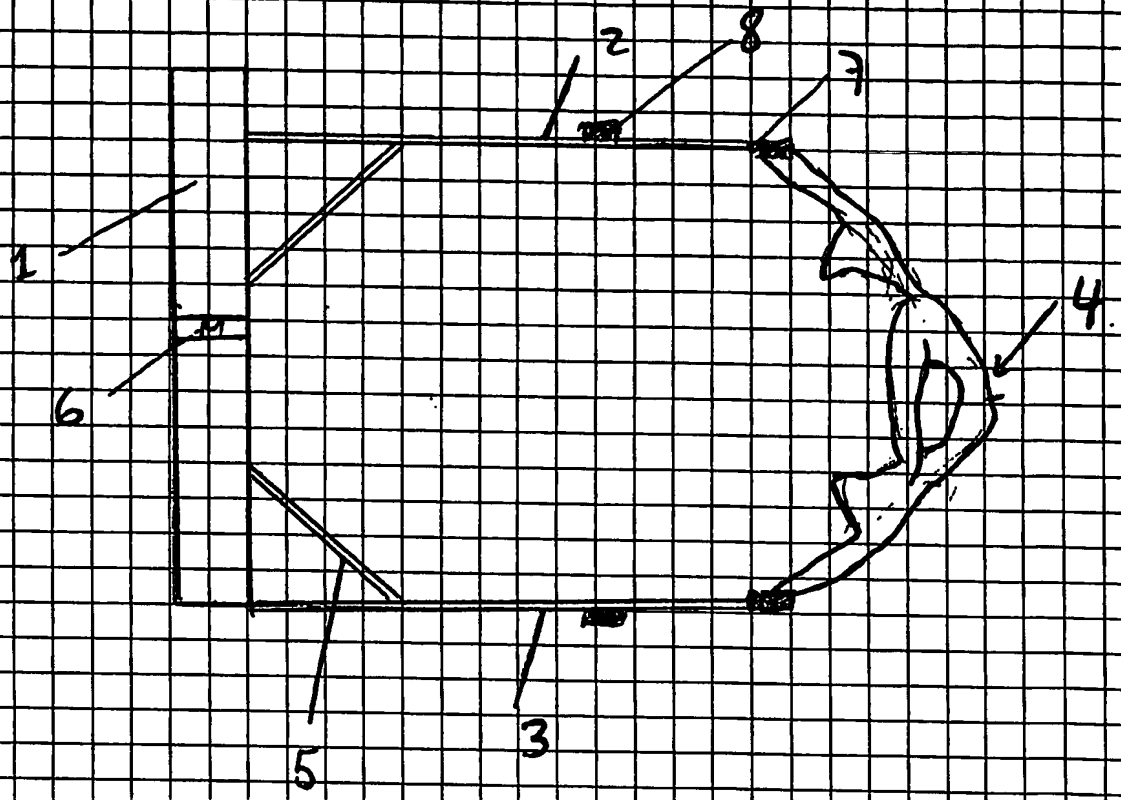


Fig 1b

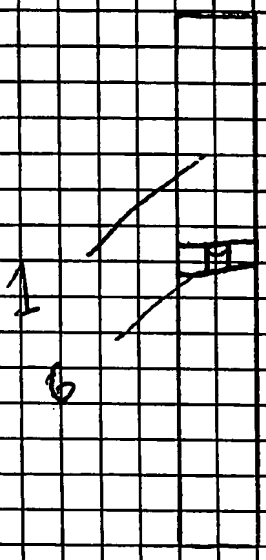


Fig 1c

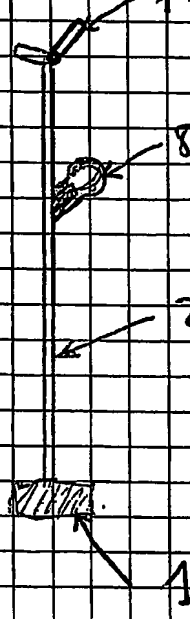


Fig 2a

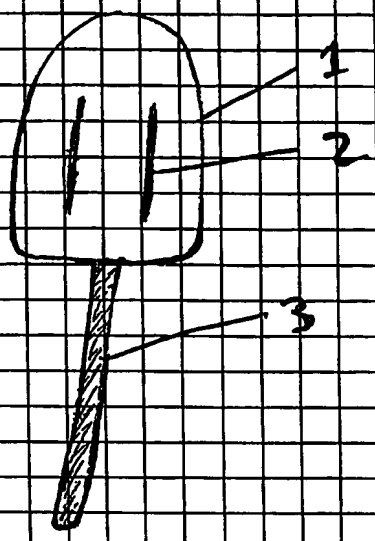


Fig 2b

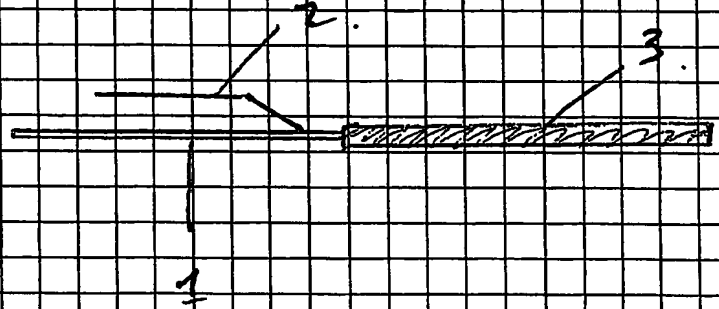


Fig 3a

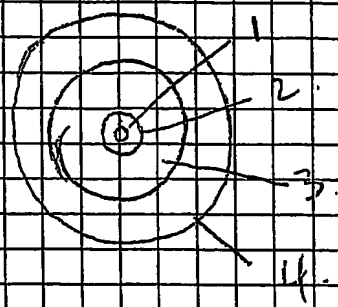


Fig 3b

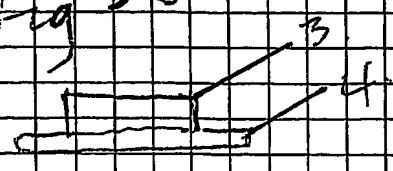


Fig 4a

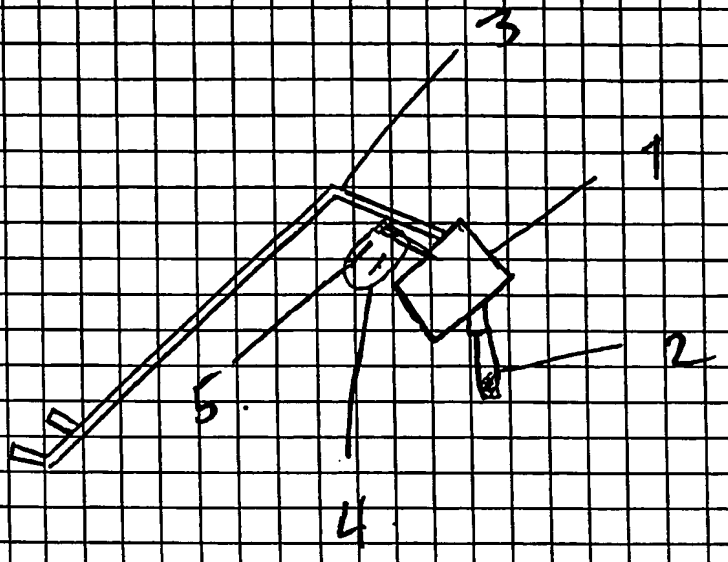
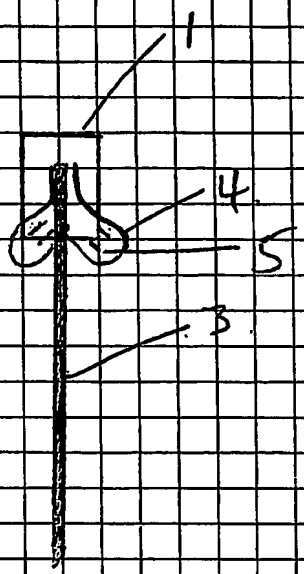


Fig 4b.



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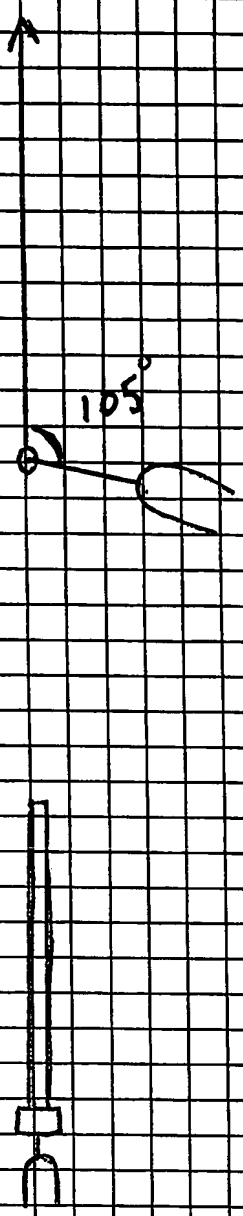


ORTHOFRIEND

Fig 5a.

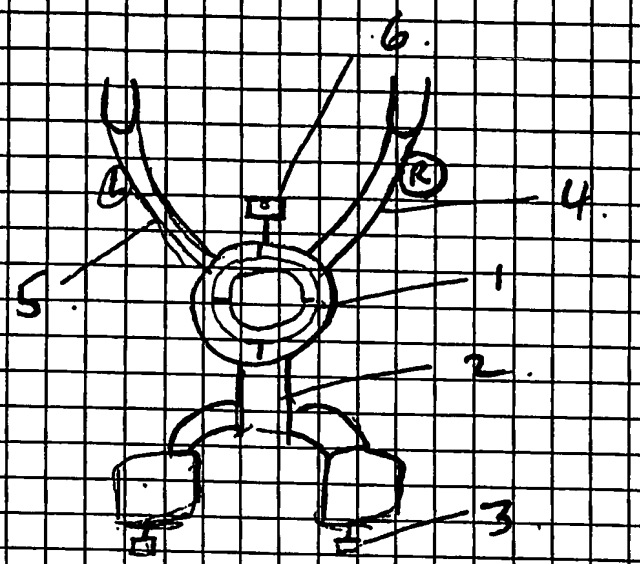
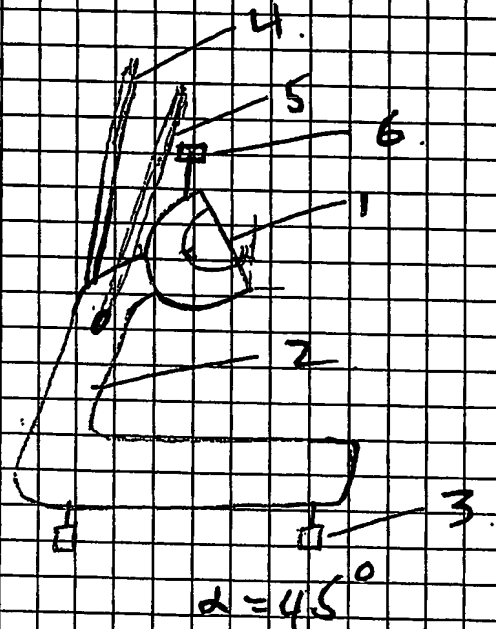


Fig 5b.



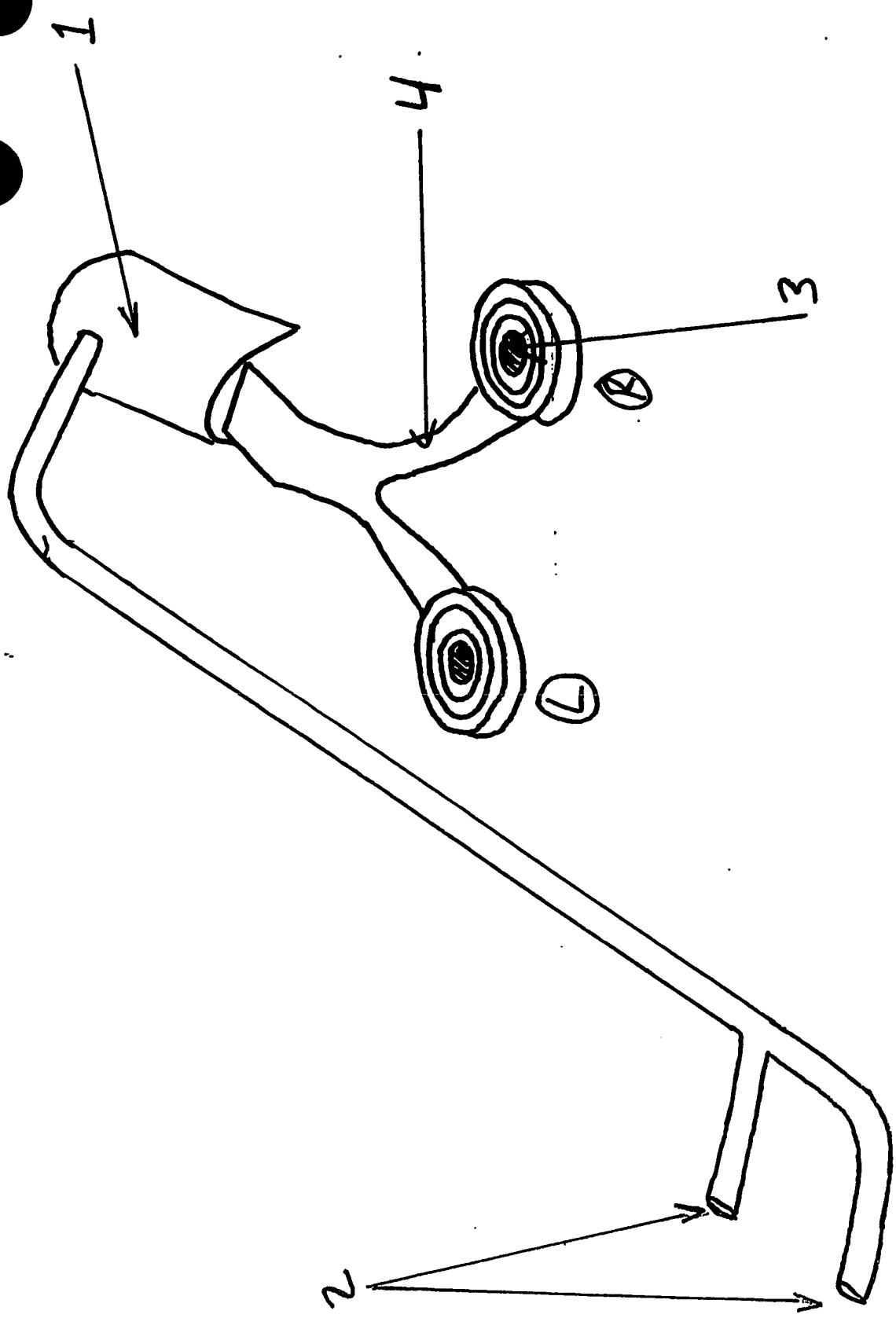
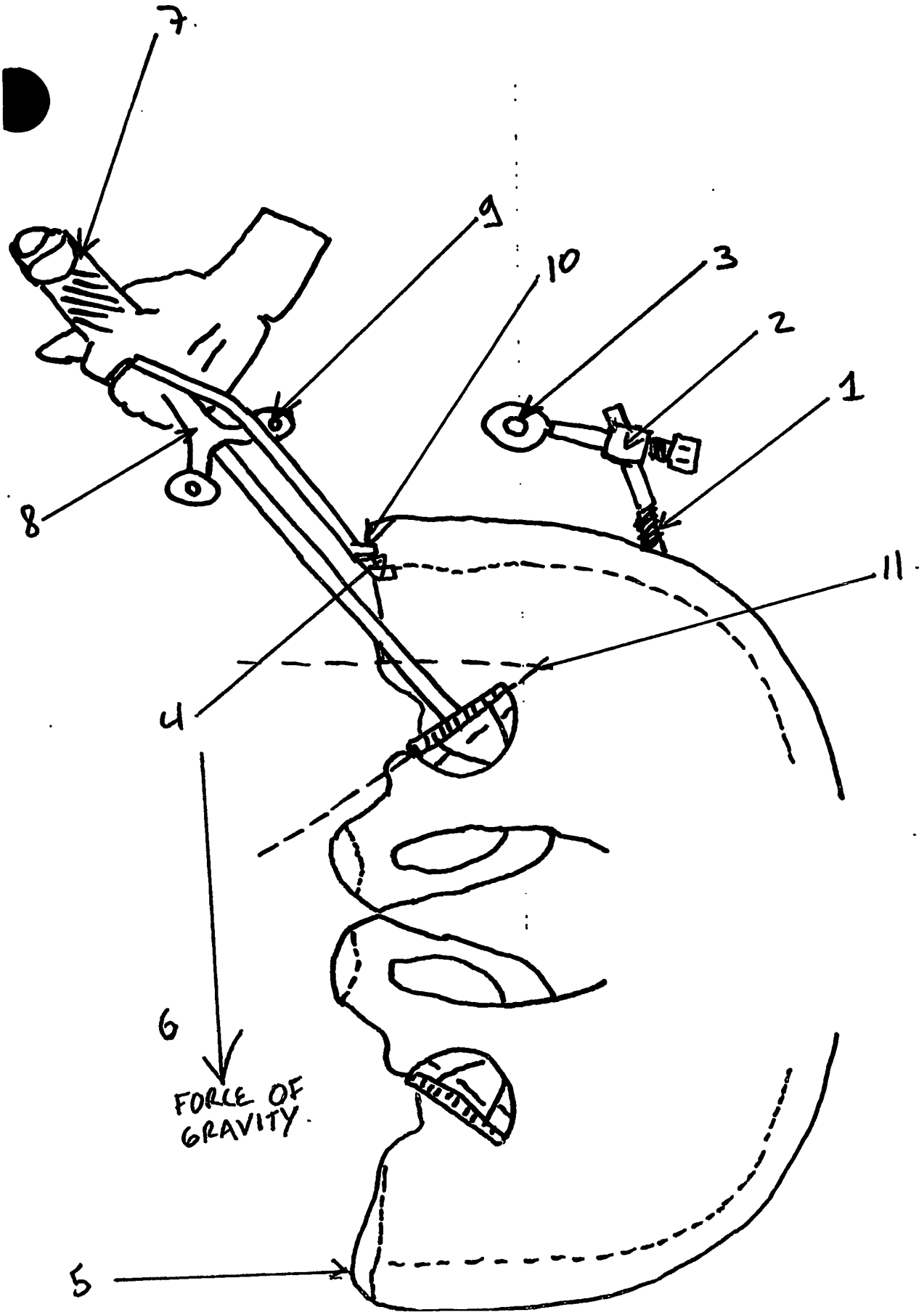


Fig. 1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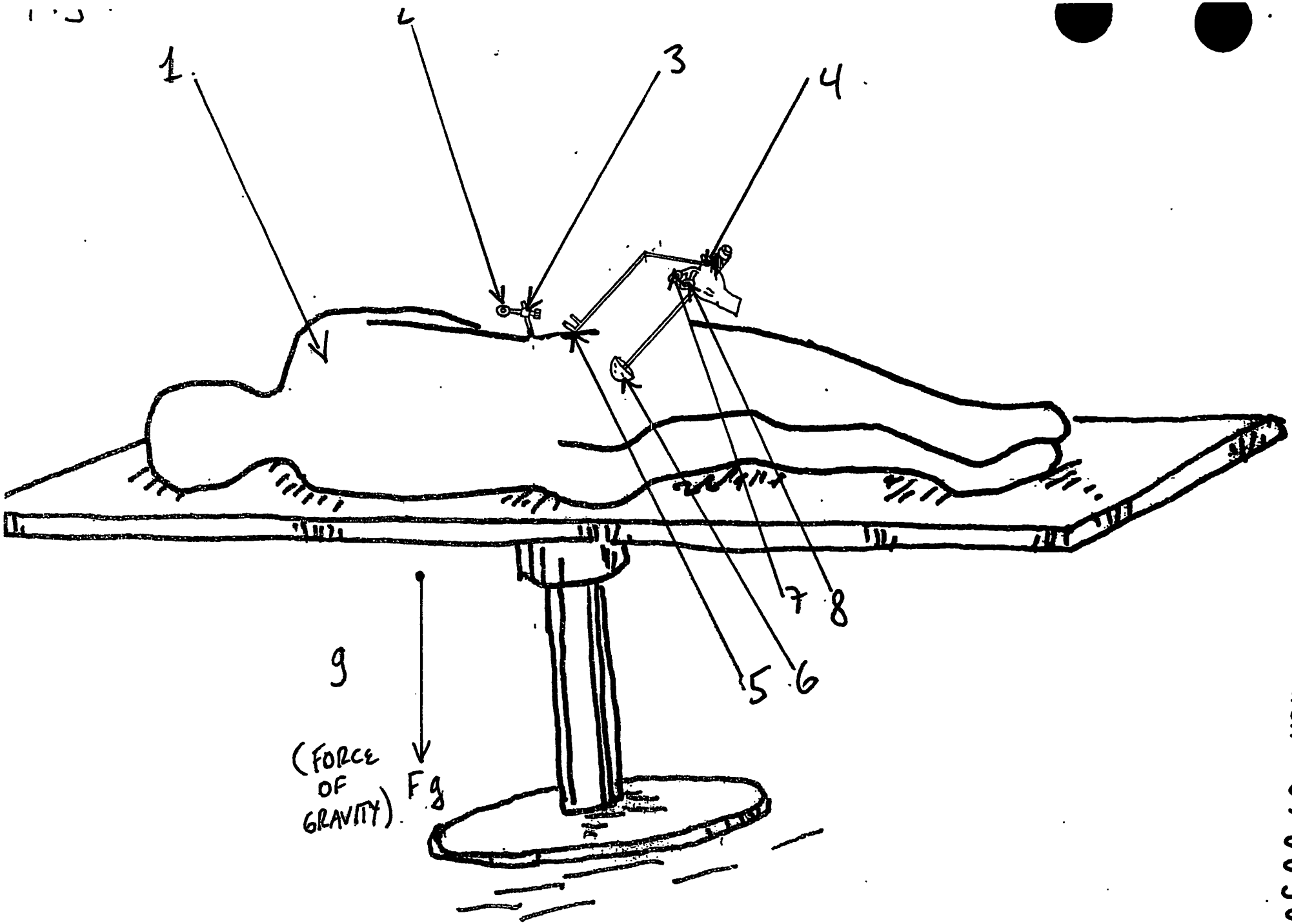

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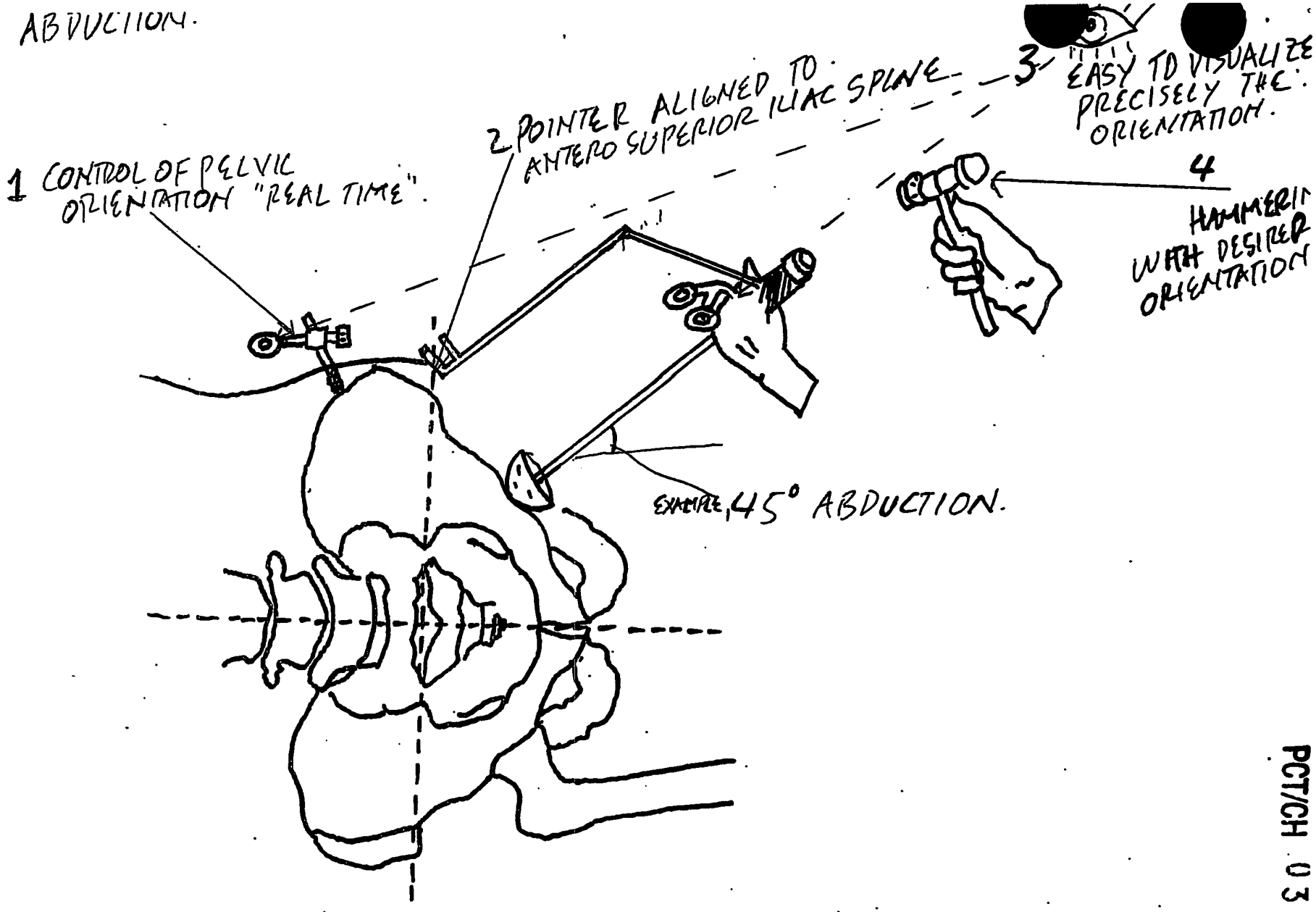
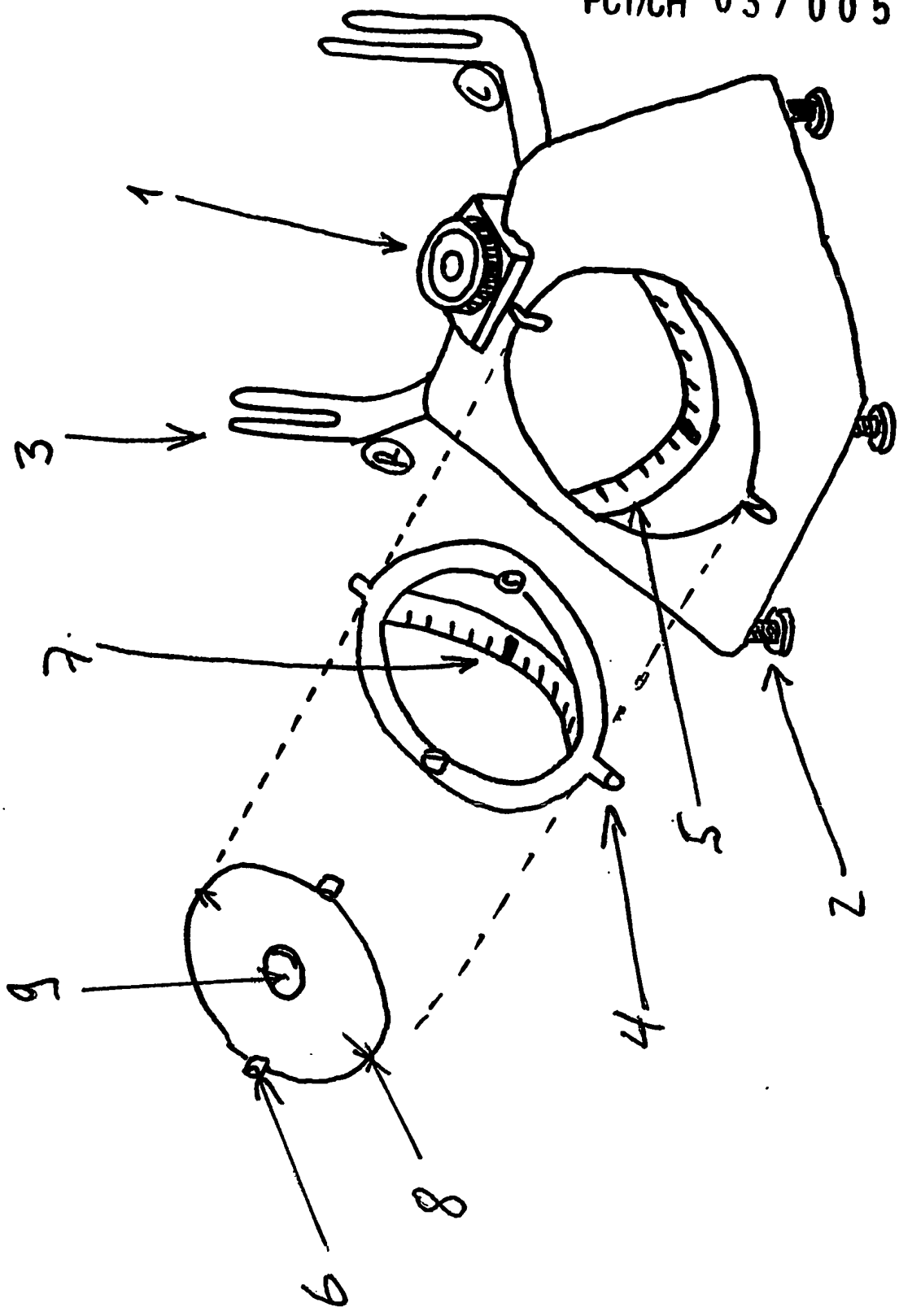
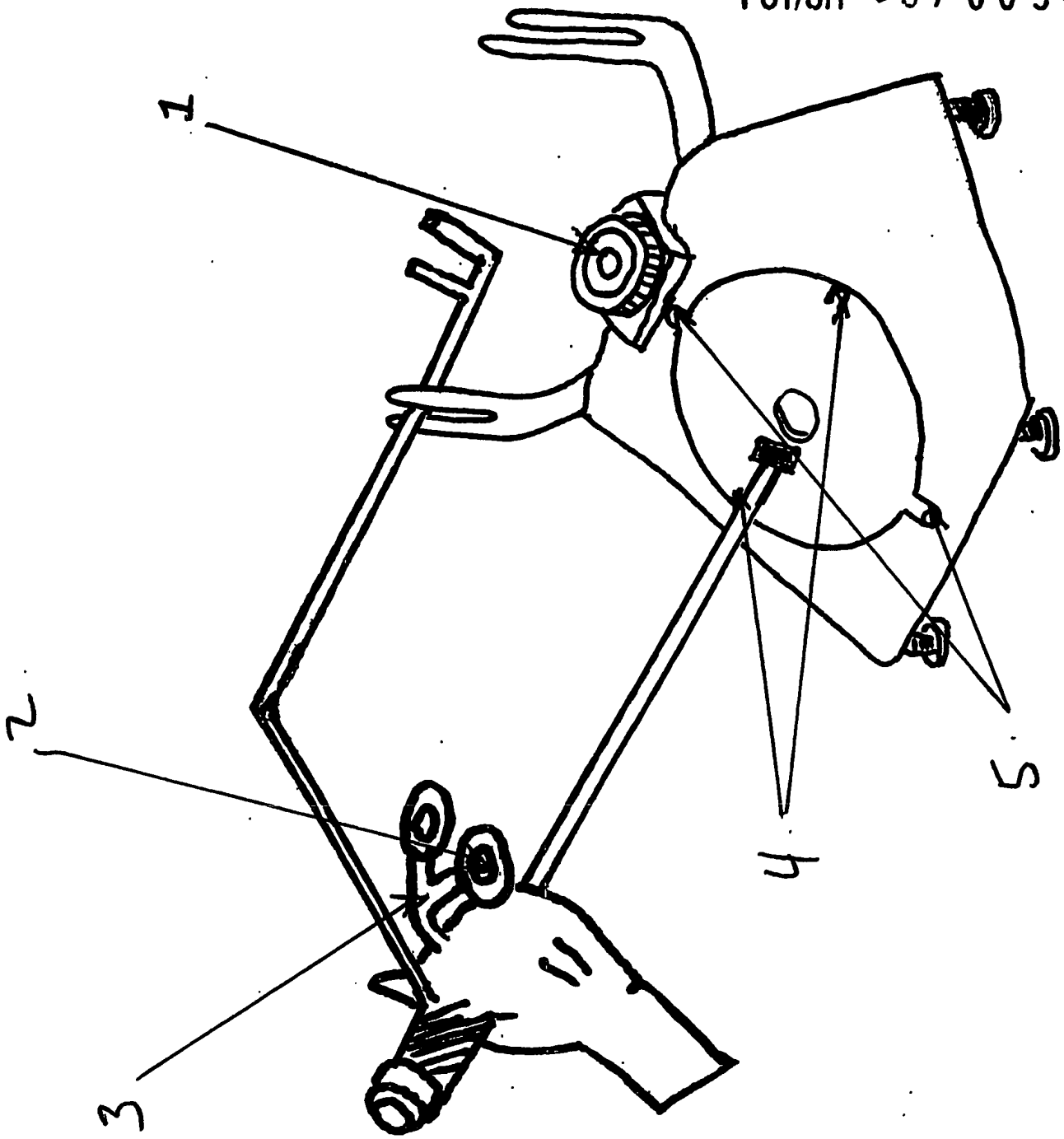




(1a)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